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Dated: September 9, 2005

Signature:

Georgina Matos
(Georgina Matos)

Patent

Docket No. 252312005704

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Stephen M. COUTTS et al.

Serial No.: 09/752,533

Filing Date: December 29, 2000

For: CONJUGATES OF CHEMICALLY
DEFINED NON-POLYMERIC
VALENCY PLATFORM MOLECULES
AND BIOLOGICALLY ACTIVE
MOLECULES (AS AMENDED)

Examiner: D. Lukton

Group Art Unit: 1653

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of a foreign document and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.

- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Included in this submission are press releases issued by La Jolla Pharmaceutical Company pertaining to Riquent (abetimus sodium; also formerly known as LJP 394 and as conjugate 20-II in Figure 6B of U.S. Serial No. 09/752,533). Conjugate 20-II is referred to in the specification and relates to compositions described and claimed. Also included in this submission are: (1) an Office Action in co-owned, co-pending application U.S. Serial No. 10/219,238; (2) an Office Action in co-owned application U.S. Serial No. 09/457,875, which was abandoned in favor of a continuation; and (3) an Office Action in co-owned application U.S. Serial No. 09/766,365 (continuation of U.S. Serial No. 09/457,875), which was abandoned in favor of a continuation. Also submitted herein is information from the regulatory agency United States Food and Drug Administration (FDA) dated October 13, 2004, addressing clinical trial data regarding a response associated with treatment relating to that disclosed in the application U.S. Serial No. 09/752,533.

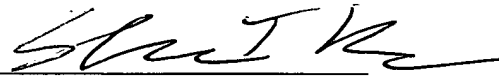
Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

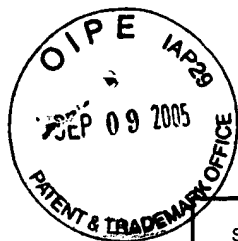
The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 252312005704.

Dated: September 9, 2005

Respectfully submitted,

By 
Shannon Reaney
Registration No.: 52,285
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5744



ALTERNATIVE TO PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/752,533
				Filing Date	December 29, 2000
				First Named Inventor	Stephen M. COUTTS
				Art Unit	1653
				Examiner Name	D. Lukton
Sheet	1	of	2	Attorney Docket Number	252312005704

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-2003/0103990-A1	06-05-2003	Coutts et al.	
	2.	US-2004/0208864-A1	10-21-2004	Strand et al.	
	3.	US-2004/0224366-A1	11-11-2004	Jones et al.	
	4.	US-2004/0258683-A1	12-23-2004	Linnik et al.	
	5.	US-2005/0004351-A1	01-06-2005	Marquis et al.	
	6.	US-2005/0026856-A1	02-03-2005	Coutts et al.	
	7.	US-2005/0031635-A1	02-10-2005	Coutts et al.	
	8.	US-6,858,210-B1	02-22-2005	Marquis et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	9.	DD-287 950-A5	03-14-1991	Akademie der Wissenschaften der DDR		√

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	10.	Calvin, N.M. et al. (1987). "Photoadducts of 8-Methoxypsoralen to Cytosine in DNA," <i>Photochemistry and Photobiology</i> 45(3):323-330.	
	11.	Food and Drug Administration (October 13, 2004). Information from United States Food and Drug Administration, 2 pages.	
	12.	La Jolla Pharmaceutical Company Press Release. (March 31, 2003). "Results From Two Riquent™ Trials Show Lupus Patients With Sustained Reductions In Antibodies To dsDNA Have Fewer Renal Flares," San Diego, CA, 4 pages.	
	13.	La Jolla Pharmaceutical Company Press Release. (February 18, 2003). "La Jolla Pharmaceutical Announces Results of Phase III Trial of Riquent™," San Diego, CA, 5 pages.	
	14.	La Jolla Pharmaceutical Company Press Release. (August 2, 2004). "La Jolla Pharmaceutical Reaches Agreement with Cardio-Renal Division of FDA Regarding Phase 4 Trial Design Under Special Protocol Assessment," San Diego, CA, 3 pages.	
	15.	La Jolla Pharmaceutical Company Press Release. (October 14, 2004). "La Jolla Pharmaceutical Company Receives Letter From FDA About Riquent," San Diego, CA, 2 pages.	
	16.	La Jolla Pharmaceutical Company Press Release. (November 23, 2004). "La Jolla Pharmaceutical Company Provides Update on Riquent Program," San Diego, CA, 3 pages.	
	17.	La Jolla Pharmaceutical Company Press Release. (March 14, 2005). "La Jolla Pharmaceutical Announces Outcome of Recent FDA Discussions," San Diego, CA, 2 pages.	
	18.	La Jolla Pharmaceutical Company Press Release. (May 31, 2005). "La Jolla Pharmaceutical Company Provides Update on Riquent," San Diego, CA, 3 pages.	
	19.	Office Action mailed on July 18, 2000 for U.S. Patent Application No. 09/457,875, 7 pages.	

Examiner Signature		Date Considered	
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pa- 1008332



ALTERNATIVE TO PTO/SB/08a/b (07-05)

Substitute Form 1449/EX-100 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/752,533
				Filing Date	December 29, 2000
				First Named Inventor	Stephen M. COUTTS
				Art Unit	1653
				Examiner Name	D. Lukton
Sheet	2	of	2	Attorney Docket Number	252312005704

	20.	Office Action mailed on October 5, 2001 for U.S. Patent Application No. 09/766,365, 5 pages.	
	21.	Office Action mailed on February 22, 2005 for U.S. Patent Application No. 10/219,238, 13 pages.	
	22.	Ostrander, E.A. et al. (1993). "Identification and Characterization of Dinucleotide Repeat (CA) _n Markers for Genetic Mapping in Dog," <i>Genomics</i> 16:207-213.	
	23.	U.S. Patent Application No. 09/724,822 filed November 28, 2000 by Linnik et al.	
	24.	U.S. Patent Application No. 10/846,079, filed May 13, 2004 by Victoria et al.	
	25.	U.S. Patent Application No. 10/957,198, filed October 1, 2004 by Barstad et al.	
	26.	U.S. Patent Application No. 11/073,332, filed March 4, 2005 by Jones.	
	27.	U.S. Patent Application No. 11/081,309 filed March 15, 2005 by Linnik et al.	
	28.	U.S. Patent Application No. 11/144,155, filed June 2, 2005 by Engle et al.	
	29.	U.S. Patent Application No. 11/149,779, filed June 10, 2005 by Jones.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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